PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Artcle 36 and Rule 70)

Applicant's or agent's file reference OPP030936KR	**FOR FURTHER ACTION**	SeeNotificationofTransmittalofInternationalPreliminary Examination Report (Form PCT/IPEA/416)
International application No. **PCT/KR2003/001666**	International filing date *(day/month/year)* **19 AUGUST 2003 (19.08.2003)**	Priority date *(day/month/year)* 19 AUGUST 2002 (19.08.2002)

International Patent Classification (IPC) or national classification and IPC

IPC7 C12N 1/20

Applicant

KOLON IND. INC. et al

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demamd	Date of completion of this report
19 MARCH 2004 (19.03.2004)	07 DECEMBER 2004 (07.12.2004)

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International aplication No.
PCT/KR2003/001666

I. Basis of the report

1. With regard to the elements of the international application:*

- [X] the international application as originally filed
- [ ] the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the claims:
  pages _____ , as originally filed
  pages _____ , as amended (together with any statment) under Article 19
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the drawings:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____
- [ ] the sequence listing part of the description:
  pages _____ , as originally filed
  pages _____ , filed with the demand
  pages _____ , filed with the letter of _____

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language English which is

- [ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- [X] the language of publication of the international application(under Rule 48.3(b)).
- [ ] the language of the translation furnished for the purposes of international preliminary examination(under Rules 55.2 and/ or 55.3).

3. With regard to any **nucleotide** and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- [ ] contained inthe international application in written form.
- [ ] filed together with the international application in computer readable form.
- [ ] furnished subsequently to this Authority in written form.
- [ ] furnished subsequently to this Authority in computer readable form
- [ ] The statement that the subsequently furnished written sequence listing does not go beyond the disc losure in the international applicationas as filed has been furinshed.
- [ ] The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. [ ] The amendments have resulted in the cancellation of:
   - [ ] the description, pages _____
   - [ ] the claims, Nos. _____
   - [ ] the drawings, sheets _____

5. [ ] This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box(Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this opinion as "originally filed." and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item I and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION

International aplication No.
PCT/KR2003/001666

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	1-4, 6-10	YES
	Claims	5	NO
Inventive step (IS)	Claims	1-4, 6-10	YES
	Claims		NO
Industrial applicability (IA)	Claims	1-10	YES
	Claims		NO

2. Citations and explanations (Rule 70.7)

The following documents have been considered for the purpose of this report:

D1: US 5,023,175 A (Kabushiki Kaisha Yakult Honsha) 1 June 1991
D2: US 4,780,414 A (Bio-Technology General Corporation) 15 November 1988

I. Novelty: claim 5

Claim 5 relates to a hyaluronic acid and a salt thereof. The same hyaluronic acid of the present invention is described in D1 and D2. Therefore, the subject matter of claim 5 is considered to lack novelty under PCT Article 33(2).

II. Novelty and Inventive Step: claim 1-4, 6-10

Claims 1-4 relate to a special strain, *Streptococcus sp.* KL0188 (KCTC 10248BP), which is a hyaluronic acid producing microorganism strain that does not express hyaluronidase and that shows a non-hemolytic property; and a method for purifying hyaluronic acid characterized by using the same microorganism.

And, claims 6-10 relate to a method for purifying hyaluronic acid comprising the steps of treating a culture solution of hyaluronic acid producing strain with an aromatic adsorption resin; treating it with an active carbon; and precipitating it with an organic solvent to purify hyaluronic acid and a salt thereof.

D1 and D2 disclose a new microorganism, *Streptococcus sp.*, for the production of hyaluronic acid; and a method for purifying hyaluronic acid comprising the steps of treating a culture solution of the same microorganism with an aromatic adsorption resin and precipitating it with an organic solvent to purify hyaluronic acid and a salt thereof.

Compared with the present invention, none of the above-mentioned prior art documents disclose the special strain of the present invention, the method of purifying hyaluronic acid using the same microorganism, and the method of purifying hyaluronic acid comprising the step of treating a culture solution with an active carbon. In addition, the present invention is not considered to be easily invented by a person skilled in the art by using the teachings of D1 and D2. Therefore, the subject matter of claims 1-4, 6-10 is considered to be novel and to involve an inventive step under PCT Article 33(2) and (3).

(Continued on Supplemental Sheet.)

Supplemental Box
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of:

Box V.

III. Industrial Applicability

There is no reason for forming a negative opinion about the industrial applicability of this invention. Consequently, claims 1-10 appear to meet the requirement of PCT Article 33(4).

IV. Clarity

Claims 3 and 8 are not considered to be obviously described, since the names therein of the aromatic adsorption resin such as HP10 and HP20, are only the names of commercial products.